

SECTION III - CFR CLASSIFICATION OF MOBILE BEARING KNEES

Based upon the information contained in this petition, the sponsor proposes the following classification text for Mobile Bearing Total Knees and Mobile Bearing Unicompartmental Knees:

Mobile Bearing Total Knee

Knee joint patellofemorotibial metal/polymer mobile bearing cemented or porous-coated, uncemented prosthesis

(a) *Identification.* A knee joint patellofemorotibial metal/polymer mobile bearing cemented or porous-coated uncemented prosthesis is a device intended to be implanted to replace a knee joint. The device permits either unconstrained or constrained rotation of the articular surface in the transverse plane and may or may not permit limited anteroposterior and/or mediolateral movement of the articular surface upon the tibial component. It has no linkage across the joint. The device may use affixed structural porous metal in place of the porous coating.

This generic type of device is designed for use with bone cement and/or to achieve biological fixation to bone without the use of bone cement.

(b) *Classification.* Class II.

Mobile Bearing Unicompartmental Knee

Knee joint femorotibial (uni-compartmental) metal/polymer mobile bearing cemented or porous-coated, uncemented prosthesis

(a) *Identification.* A knee joint femorotibial (uni-compartmental) metal/polymer mobile bearing cemented or porous-coated, uncemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device permits either unconstrained or constrained rotation of the articular surface in the transverse plane and may or may not permit limited anteroposterior and/or mediolateral movement of the articular surface upon the tibial component. It has no linkage across the joint. The device may also use affixed structural porous metal in place of the porous coating.

This generic type of device is designed for use with bone cement and/or to achieve biological fixation to bone without the use of bone cement.

(b) *Classification.* Class II.